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**UNITED STATES DISTRICT COURT**

**NORTHERN DISTRICT OF CALIFORNIA**

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| Karla Rodriguez and Edward Rodriguez, Individually and as Parents and Natural Guardians of Maia Rodriguez, a Minor,<br><br>Plaintiffs,<br>v.<br><br>GlaxoSmithKline LLC d/b/a GlaxoSmithKline,<br>Defendant, | Case No.: _____<br><br>**COMPLAINT FOR DAMAGES**<br>**1. Negligence**<br>**2. Negligence *Per Se***<br>**3. Strict Products Liability**<br>**4. Fraudulent Misrepresentation**<br>**5. Fraudulent Concealment**<br>**6. Negligent Misrepresentation**<br>**7. Breach of Express Warranty**<br>**8. Breach of Implied Warranty of Merchantability and Fitness for a Particular Use**<br><br>**DEMAND FOR JURY TRIAL** |

Plaintiffs, Karla Rodriguez and Edward Rodriguez, Individually and as Parents and Natural Guardians ("Parent Plaintiffs") on behalf of Maia Rodriguez, a Minor ("Minor Plaintiff") (collectively "Plaintiffs") by and through their undersigned counsel, hereby submit this Complaint and Jury Demand against Defendant, GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("GSK" or "Defendant") for compensatory damages, punitive damages, equitable relief and such other relief deemed just and proper arising from the injuries to Maia Rodriguez as a result of prenatal exposure to the prescription drug Zofran®. In support of this Complaint and Jury Demand, Plaintiffs allege the following:

## Introduction

1. Zofran® is a blockbuster drug developed by GSK to treat only those patients who were afflicted with the most severe nausea imaginable— the type of nausea suffered as a result of chemotherapy or radiation treatments in cancer patients and/or postoperative nausea and vomiting.

2. The U.S. Food and Drug Administration ("FDA") approved Zofran® (ondansetron hydrochloride) in January 1991 for use in cancer patients who required chemotherapy or radiation treatment.

3. Although the only FDA approval for this drug was for seriously ill patients, GSK marketed Zofran® "off-label" since approximately 1998 as an established safe and effective treatment for the very common side effect of a normal pregnancy— pregnancy related nausea and vomiting, commonly known as "morning sickness."

4. GSK further marketed Zofran® during this time as a "wonder drug" for pregnant women, despite having knowledge that such representations were false and misleading since GSK had never undertaken a single study establishing that this powerful drug, Zofran®, was safe or effective for pregnant mothers and their growing children *in utero*. Unlike the manufacturer of another anti-nausea prescription drug that was on the market and available with FDA approval in the United States for treating pregnancy related nausea, GSK never conducted a single clinical trial establishing the safety and efficacy of Zofran® (ondansetron hydrochloride) for treatment of nausea and/or vomiting during pregnancy before GSK marketed Zofran® to pregnant women and their healthcare providers for such treatment. In fact, GSK excluded pregnant women from its clinical trials used to support its application for FDA approval of Zofran® (ondansetron hydrochloride) in the 1990s.

5. GSK chose not to study Zofran® in pregnant women or seek FDA approval to market the drug for treatment during pregnancy for pregnancy related nausea. GSK avoided conducting these studies and buried any internal analyses of the teratogenic potential of Zofran® (ondansetron hydrochloride) because it would have hampered its marketing of Zofran® and decreased profits by linking the drug to severe birth defects.

6. As a result of GSK's nationwide fraudulent marketing campaign to healthcare providers, Zofran® was prescribed to unsuspecting pregnant women. In fact, in the 2000s Zofran® became the number one most prescribed drug for treating pregnancy related nausea in the United States. Pregnant women ingested the drug because they innocently believed that Zofran® was an appropriate, safe and effective drug for use in their circumstance. When pregnant women ingested Zofran® they had no way of knowing that Zofran® had never been studied in pregnant women, much less any way of knowing that it had not been shown to be a safe treatment for pregnancy related nausea. Zofran® would never have become the most prescribed drug for pregnancy related nausea in the United States and Plaintiff, Karla Rodriguez, would never have taken it if GSK had not marketed the drug "off-label" as a safe and effective treatment for pregnancy related nausea and/or vomiting through false and misleading promotion and communication.

7. GSK knew that Zofran® was unsafe for ingestion by expectant mothers.

8. In the 1980s, GSK conducted animal studies which revealed evidence of toxicity, intrauterine deaths and malformations in offspring. These outcomes further showed that the active ingredient in Zofran®, ondansetron hydrochloride, crossed the placental barrier of pregnant mammals to the fetuses.

9. A later study conducted in humans confirmed that Zofran® (ondansetron hydrochloride) crossed the human placental barrier exposing fetuses to substantial concentrations of Zofran® *in utero*.

10. GSK did not disclose the outcomes of the animal studies to women of childbearing age, pregnant women or their treating healthcare providers.

11. In 1992, GSK began receiving mounting evidence of reports of birth defects associated with Zofran®. GSK had received at least 32 such reports by the year 2000. To date, GSK has received more than 200 such reports including reports of similar congenital anomalies suffered by Minor Plaintiff, Maia Rodriguez. GSK never disclosed these reports to women of childbearing age, pregnant women or their healthcare providers.

12. Scientists have conducted large-scale epidemiological and mechanistic studies that have demonstrated an elevated risk of developing birth defects, such as those suffered by Minor Plaintiff, Maia Rodriguez, after being exposed to Zofran® *in utero*.

13. In 2012, GSK pled guilty to criminal charges lodged by the United States Department of Justice for its "off-label" promotion of several of its drugs for indications that were not approved by the FDA, including Zofran®. In exchange for GSK's full performance of its criminal plea agreement with the U.S. Department of Justice and for certain other promised exchanges between GSK and the U.S. Department of Justice, the U.S. Department of Justice agreed not to criminally prosecute GSK for conduct relating to "GSK's sales, marketing and promotion of … Zofran between January 1998 and December 2004." [Agreement between United States and GSK, pp. 1-2, June 27, 2012]

14. Around the same time, GSK entered into civil settlements with the United States that

included more than $1 Billion in payments to the federal government for its "off-label" marketing of various prescription drugs, including Zofran®.

15. GSK's civil settlement agreement with the United States states that: "During the period January 1, 2002 through December 31, 2004, GSK knowingly:

(a) promoted the sale and use of Zofran for a variety of conditions other than those for which its use was approved as safe and effective by the FDA (including hyperemesis or pregnancy-related nausea); …

(b) made and/or disseminated unsubstantiated and/or false representations or statements about the safety and efficacy of Zofran concerning the uses described in section (a) of this subparagraph [hyperemesis and pregnancy-related nausea]; and

(c) offered and paid illegal remuneration to health care professionals to induce them to promote and prescribe Zofran..."

(Settlement Agreement, p. 5, July 2, 2012)

16. GSK's conduct has caused devastating, irreversible and lifelong consequences and suffering to innocent children and their families, including the Plaintiffs herein.

17. Karla Rodriguez was prescribed and took Zofran® during her pregnancy in 2004. Because Mrs. Rodriguez and her doctor did not know that Zofran® could cause birth defects, she was prescribed Zofran® in order to help with pregnancy related nausea and vomiting

18. On November 28, 2004, Karla gave birth to her daughter, Maia Rodriguez, via cesarean section.

19. Immediately after Maia was born, doctors told Karla that her daughter's heart had not formed correctly. Maia was born with pulmonary atresia with dysplastic tricuspid valve.

20. There is no history of birth defects in the Rodriguez family.

21. Maia was admitted to the neonatal intensive care unit ("NICU") at one day of life and

transferred to Lucile Packard Children's Hospital. Maia remained in the NICU at Lucile Packard until she was 10 days old.

22. Two days after she was born, Maia underwent a balloon valvuloplasty at Lucile Packard.

23. On January 14, 2005, Maia underwent a cardiac catheterization.

24. On February 1, 2005, Maia underwent open heart surgery. Specifically, Maia underwent a tricuspid valve repair with minimal residual tricuspid regurgitation, transannular right ventricular outflow tract patch, partial atrial septal defect("ASD") closure, right ventricular outflow tract muscle resection, reduction of the right atrium and patent ductus arteriosus ligation.

25. As a result of her pulmonary atresia resulting in this complex open heart surgery, Maia remained hospitalized from February 1, 2005 until February 12, 2005.

26. As a baby and throughout her childhood, Maia's doctors have closely monitored her heart. Her heart monitoring continues every six to twelve months and she will be followed for her entire life.

27. In fact, Maia is expected to need further surgery as she gets older.

28. Maia Rodriguez was exposed to Zofran® *in utero* during the periods of gestation when her heart was forming and susceptible to developmental insult or interruption from *in utero* exposure to Zofran®.

29. Had Mrs. Rodriguez or her healthcare providers known the truth about Zofran® and the unreasonable risk of harm, long concealed and misrepresented by GSK, then Karla Rodriguez would never have taken and her healthcare providers would not have prescribed Zofran® for pregnancy related nausea and vomiting.

30. As a direct and proximate result of GSK's negligent conduct, Maia Rodriguez was born with a severe heart defect and endured pain and suffering, mental anguish, medical expenses and other economic and non-economic damages and will require continuous medical monitoring and treatment.

31. Plaintiffs bring claims for compensatory damages, punitive damages, equitable relief and such other relief deemed just and proper arising from the injuries set out herein to ensure that similarly situated women of childbearing age, pregnant women and their healthcare providers are fully informed about the risks, benefits and alternative drugs marketed and available for safe and effective use in pregnant women suffering from pregnancy related nausea.

**Parties**

32. Plaintiffs, Karla Rodriguez and Edward Rodriguez, are the parents and natural guardians of Minor Plaintiff, Maia Rodriguez.

33. Plaintiffs currently reside in Texas.

34. Karla Rodriguez ingested Zofran® during her pregnancy with Maia Rodriguez while residing in California.

35. Maia Rodriguez was born in Santa Cruz, California on November 28, 2004.

36. Maia Rodriguez was diagnosed with pulmonary atresia with dysplastic tricuspid valve in Santa Cruz, California.

37. At all times relevant herein, Plaintiffs were residents of California.

38. GlaxoSmithKline LLC d/b/a GlaxoSmithKline ("GSK") is a limited liability company organized under the laws of Delaware. GSK's sole member is GlaxoSmithKline Holdings, Inc., which is also a Delaware corporation that has identified its principal place of business in Wilmington, Delaware.

39. GSK is the successor in interest to Glaxo, Inc. and Glaxo Wellcome Inc. Glaxo, Inc. was the sponsor for the original New Drug Application ("NDA") for Zofran® in the 1990s. Glaxo, Inc., through its division Cerenex Pharmaceuticals, authored the original package insert and labeling for Zofran®, including the warnings and precautions sections. Glaxo Wellcome Inc. sponsored additional NDAs for Zofran®, monitored and evaluated post-market adverse event reports arising from Zofran® and authored additional product labeling, including the warnings and precautions therein.

40. GSK may be served with process by registered mail, with return receipt requested, upon Corporation Service Company, 2711 Centerville Road, Wilmington, Delaware, 19808.

41. For purposes of this complaint and jury demand, GSK refers to GlaxoSmithKline LLC d/b/a/ GlaxoSmithKline and any and all of its predecessors, including but not limited to Glaxo, Inc. and Glaxo Wellcome Inc., and affiliates that discovery reveals were involved in the testing, designing, developing, manufacturing, promoting, marketing, selling and/or distributing Zofran®.

42. GSK regularly conducts business in the States of Delaware, California and throughout the United States and derives substantial revenues and benefits from drugs it sells in the States of Delaware, California and throughout the United States. GSK is engaged in the business of testing, designing, developing, manufacturing, promoting, marketing, selling and/or distributing pharmaceutical drugs, including the drug Zofran® in Delaware, California and throughout the United States,

**Jurisdiction and Venue**

43. This Court has jurisdiction over this action pursuant to U.S.C. § 1332 because the parties are citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of interest and costs.

44. Plaintiff, Karla Rodriguez, ingested Zofran® during her pregnancy with Maia Rodriguez while residing in California, Maia was born in California and her injuries were diagnosed in California. GSK is a citizen of Delaware for purposes of this action.

45. Venue is proper under 28 U.S.C. § 1391 because a substantial part of the events or omissions giving rise to the claims herein occurred in California and this District.

**Background on Zofran®**

46. Zofran® is a prescription drug indicated for the prevention of chemotherapy-induced nausea and vomiting, radiation therapy-induced nausea and vomiting and post-operative nausea and/or vomiting:

**INDICATIONS AND USAGE**

1. Prevention of nausea and vomiting associated with highly emetogenic **cancer chemotherapy**, including cisplatin ≥ 50 mg/m2.
2. Prevention of nausea and vomiting associated with initial and repeat courses of moderately emetogenic **cancer chemotherapy**.
3. Prevention of nausea and vomiting associated with **radiotherapy** in patients receiving either total body irradiation, single high-dose fraction to the abdomen, or daily fractions to the abdomen.
4. Prevention of **postoperative nausea and/or vomiting**.

(GSK, Zofran Prescribing Information, September 2014) (emphasis added)

47. The medical term for nausea and vomiting is emesis and drugs that prevent or treat nausea and vomiting are called antiemetics.

48. Zofran® is part of a class of antiemetics called selective serotonin 5-$HT_3$ receptor antagonists. The active ingredient in Zofran® is ondansetron hydrochloride which is a potent and selective antagonist at the 5-hydroxytryptamine receptor type 3 ("5-$HT_3$").

49. Although 5-hydroxytryptamine ("5-HT") occurs in most tissues of the human body, Zofran® is believed to block the effect of serotonin at the 5-$HT_3$ receptors located along vagal afferents in the gastrointestinal tract and at the receptors located in the area postrema of the central

nervous system (the structure in the brain that controls vomiting), i.e. Zofran® antagonizes or inhibits the body's serotonin activity which triggers nausea and vomiting.

50. Zofran® was the first 5-$HT_3$ receptor antagonist approved for marketing in the United States. Other drugs in the class of 5-$HT_3$ receptor antagonists include Kytril® (granisetron) (FDA-approved 1994), Anzemet® (dolasetron) (FDA-approved 1997) and Aloxi® (palonosetron) (FDA-approved 2003).

51. Zofran® is available as an injection (2 mg/mL), a premixed injection (32 mg/50ml and 4 mg/50 ml), oral tablets (4 mg, 8 mg and 24 mg), orally disintegrating tablets (4 mg and 8 mg) and an oral solution (4 mg/5mL).

52. More specifically, GSK has obtained FDA approval for the following formations of Zofran®:

a. NDA 20-007 – Zofran® Injection (FDA approved January 4, 1991)
b. NDA 20-103 – Zofran® Tablets (FDA approved December 31, 1992)
c. NDA 20-403 – Zofran® Premixed Injection (FDA approved January 31, 1995)
d. NDA 20-605 – Zofran® Oral Solution (FDA approved January 24, 1997)
e. NDA 20-781 – Zofran® (a/k/a/ Zofran-Zydis) Orally Disintegrating Tablets (FDA approved January 27, 1999)

53. GSK has never applied for an indication for treatment of pregnancy related nausea and the FDA has never approved Zofran® for the treatment of pregnancy related nausea and vomiting or any other condition in pregnant women.

54. For GSK to market Zofran® lawfully for the treatment of pregnancy related nausea in pregnant women, it must first adequately test the drug (including performing appropriate clinic studies) and formally submit to the FDA evidence demonstrating that the drug is safe and effective for the treatment of pregnancy related nausea and vomiting.

55. A team of FDA physicians, statisticians, chemists, pharmacologists, microbiologists and other scientists would then have an opportunity to (a) review the company's data and evidence

supporting the request for approval to market the drug and (b) determine whether to approve the company's request to market the drug in the manner requested. Without first obtaining approval to market a drug for the treatment in pregnant women, a pharmaceutical company may not legally market its drug for that purpose.

56. GSK has not performed any clinical studies of Zofran® use in pregnant women; however, GSK had the resources and know-how to perform such studies and such studies were performed to support another prescription drug that, unlike Zofran®, was FDA-approved for the treatment of pregnancy related nausea.

57. GSK has not submitted to the FDA any data demonstrating the safety or efficacy of Zofran® for treating pregnancy related nausea and vomiting. Instead, GSK has illegally circumvented the FDA's approval process by marketing Zofran® for the treatment of pregnancy related nausea without applying for the FDA's approval to market Zofran® to treat pregnancy related nausea or any other condition in pregnant women. This practice is known as "off-label" promotion and in this case it constitutes false and misleading promotion and communication.

58. At all relevant times, GSK was in the business of and did test, design, research, develop, manufacture, package, promote, label, advertise, market, sell and/or distribute Zofran®.

**GSK's Knowledge that Zofran® Presents an Unreasonable Risk of Harm to Babies Who Are Exposed to it *in utero***

59. Since at least the 1980s when GSK received the results of the preclinical studies that it submitted in support of Zofran's® NDA 20-007, GSK has known of the risk that Zofran® ingested during pregnancy in mammals crosses the placental barrier to expose the fetus to the drug and its active ingredient. For example, at least as early as the mid-1980s, GSK performed placental-transfer studies of Zofran® in rats and rabbits and reported that the rat and rabbit fetuses were exposed prenatally to Zofran® during pregnancy.

60. The placental transfer of Zofran® during human pregnancy at concentrations high enough to cause congenital malformations has been independently confirmed and detected in every sample of fetal tissue taken in a published study involving 41 pregnant patients. The average fetal tissue concentration of Zofran's® active ingredient was 41% of the corresponding concentration in the mother's plasma after exposure.

61. GSK reported four animal studies in support of its application for approval of NDA 20-007: (1) Study No. R10937 I.V. Segment II teratological study of rats; (2) Study No. R10873 I.V. Segment II teratological study of rabbits; (3) Study No. R10590 Oral Segment II teratological study of rats; and (4) Study No. L10649 Oral Segment II teratological study of rabbits. These preclinical teratogenicity studies in rats and rabbits were stated by the sponsor, GSK, to show no harm to the fetus, but the data also revealed clinical signs of toxicity, premature births, intrauterine fetal deaths and impairment of ossification (incomplete bone growth).

62. Study No. R10937 was a Segment II teratological study of pregnant rats exposed to Zofran® injection solution. Four groups of 40 pregnant rats (160 total) were reportedly administered Zofran® through intravenous (I.V.) administration at doses of 0, 0.5, 1.5 and 4 mg/kg/day, respectively. Clinical signs of toxicity that were observed in the pregnant rats included "low posture, ataxia, subdued behavior and rearing, as well as nodding and bulging eyes." No observations were reported as teratogenic effects.

63. Study No. R10873 was a Segment II teratological study of pregnant rabbits exposed to Zofran® injection solution. Four groups of 15 pregnant rabbits (60 total) were reportedly given Zofran® doses of 0, 0.5, 1.5 and 4 mg/kg/day, respectively. In this study, there was a reported increase in the number of intra-uterine deaths in the 4 mg/kg group versus the lower-dose groups. The study also reported maternal weight loss in the exposed groups. Developmental retardation in

off-spring and fetuses were noted— namely, areas of the parietal (body cavity) were not fully ossified and the hyoid (neck) failed to completely ossify.

64. Study No. R10590 was an Oral Segment II teratological study of rats. Four groups of 30 pregnant rats (120 total) were given Zofran® orally at doses of 0, 1, 4 and 15 mg/kg/day, respectively. Subdued behavior, labored breathing (which is a symptom of congenital heart defects) and dilated pupils were observed in the 15 mg/kg/day group. Body weight, gestational duration and fetal examinations were reported as normal, but "slight retardation in skeletal ossification" was noted in the offspring.

65. Study No. L10649 was an Oral Segment II teratological study of rabbits. Four groups of 14-18 pregnant rabbits (56-64 total) were given Zofran® orally at doses of 0, 1, 5.5 and 30 mg/kg/day. The study reported lower maternal weight gain in all of the exposed groups as well as premature delivery and "total litter loss," referring to fetal deaths during pregnancy in the 5.5 mg/kg/day group. Examination of the fetuses showed "slight developmental retardation as evident by incomplete ossification or asymmetry of skeleton."

66. Therefore, GSK has been aware since at least when it began marketing and selling Zofran® that it could not responsibly rely on its animal studies as a basis for promoting Zofran® use in pregnant women; however, that is exactly what GSK did.

**Early Reports to GSK of Zofran®-Related Birth Defects to GSK**

67. As early as 1992, GSK began receiving reports of birth defects associated with the use of Zofran® by pregnant women.

68. By 2000, GSK had received at least 32 reports of birth defects arising from Zofran® treatment in pregnant women. These reports included congenital heart disease, dysmorphism,

intrauterine death, stillbirth, kidney malformation, congenital diaphragmatic anomaly, congenital musculoskeletal anomalies and orofacial anomalies among others.

69. In many instances, GSK received multiple reports in the same month, same week and even the same day. For example, on or about September 13, 2000, GSK received three separate reports involving Zofran® use and adverse events. For two of those incidents the impact on the baby was so severe that the baby died.

70. From 1992 to the present, GSK has received more than 200 reports of birth defects in children who were exposed to Zofran® during pregnancy.

71. The most commonly reported birth defects arising from Zofran® use during pregnancy and reported to GSK were congenital heart defects though multiple other defects such as orofacial defects, intrauterine death, stillbirth and severe malformations in newborns were frequently reported.

72. The number of events actually reported to GSK constitutes only a small fraction of the actual incidents.

**Epidemiological studies Examining the Risk of Congenital Herat Defects in Babies Who Were Exposed to Zofran® During Pregnancy**

73. Epidemiology is a branch of medicine focused on studying the causes, distribution and control of diseases in human populations.

74. Three recent epidemiological studies have examined the association between prenatal exposure to Zofran® and the risk of congenital heart defects in babies. These studies include: (1) Pasternak, et al., *Ondansetron in Pregnancy and Risk of Adverse Fetal Outcomes*, New England Journal of Medicine (Feb. 28, 2013) (the "Pasternak Study"); (2) Andersen, et al., *Ondanestron Use in Early Pregnancy and the Risk of Congenital Malformations – A Register Based Nationwide Cohort Study*, presented at International Society of Pharmaco-epidemiology, Montreal, Canada (2013) (the

"Andersen Study"); and (3) Danielsson, et al., *Use of Ondansetron During Pregnancy and Congenital Malformations in the Infant*, Elsevier, Reproductive Toxicology (Oct. 31, 2014) (the "Danielsson Study").

75. Each of these studies includes methodological characteristics tending to bias its results toward under-reporting the true risk of having a child with a birth defect. Notwithstanding these characteristics biasing the results toward the null hypothesis, all three studies show elevated risk rations for cardiac malformations including risk ratios greater than 2.0. In other words, the studies report that a pregnant woman ingesting Zofran® during pregnancy had more than a doubled risk of having a baby with a congenital heart defect and/or oral cleft as compared to a pregnant woman who did not ingest Zofran® during pregnancy.

76. The Pasternak Study included data from the Danish National Birth Registry and examined the use of Zofran® during pregnancy and risk of adverse fetal outcomes. Adverse fetal outcomes were defined as spontaneous abortion, stillbirth, any major birth defect, pre-term delivery, low birth weight and small size for gestational age. The study examined 608,385 pregnancies between January 2004 and March 31, 2011. The unexposed group was defined as women who did not fill a prescription for ondansetron during the exposure time window. The exposure time window was defined as the first 12 week gestational period. Notably, the median fetal age at first exposure to Zofran was ten weeks meaning that half of these cases were first exposed to Zofran® after organogenesis (organ formation). This characteristic of the study led to an under-reporting of the actual risk of prenatal Zofran® exposure. The study's supplemental materials indicated that women taking Zofran® during the first trimester compared to women who did not take Zofran® were 22% more likely to have offspring with a septal defect, 41% more likely to have offspring with a

ventricular septal defect and greater than four times more like to have offspring with atrioventricular septal defect.

77. The Andersen Study was also based on data collected from the Danish Medical Birth Registry and the National Hospital Register, the same data examined in the Pasternak Study. The Andersen Study examined the relationship between Zofran® use during the first trimester and subgroups of congenital malformations. Data from all women giving birth in Denmark between 1997 and 2010 were included in the study. A total of 903,207 births were identified in the study period with 1,368 women filling prescriptions for Zofran® during the first trimester. The Andersen Study therefore used a larger data set (13 years) compared to the Pasternak Study (seven years). Exposure to the drug was also defined as filling a prescription during the first trimester and prescription data was obtained from the National Prescription Registry. The Andersen Study reported that mothers who ingested Zofran® during their first trimester of pregnancy were more likely to have a child with a congenital heart defect and a two to four fold greater risk of having a baby with a septal cardiac defect.

78. The Danielsson Study investigated risks associated with Zofran® use during pregnancy and risk of cardiac congenital malformations from data available through the Swedish Medical Birth Registry. The Swedish Medical Birth Registry was combined with the Swedish Register of Prescribed Drugs to identify 1,349 infants born to women who had taken Zofran® in early pregnancy from 1998-2012. The total number of births in the study was 1,501,434 infants and 43,658 had malformations classified as major (2.9%). Among the major malformations, 14,872 had cardiovascular defects (34%) and 10,491 had a cardiac septum defect (24%). The Danielsson Study reported a statistically significantly elevated risk for cardiovascular defects for mothers taking Zofran® versus those who did not. The results reported that the mothers who took Zofran® during

early pregnancy had a 62% increased risk of having a baby with a cardiovascular defect. Further, mothers who took Zofran® during pregnancy had a greater than two-fold increased risk of having a baby with a septal cardiac defect compared to mothers who did not take Zofran® during pregnancy.

79. In summary, GSK has had mounting evidence showing that Zofran® presents an unreasonable risk of harm to babies who are exposed to the drug during pregnancy. GSK has been aware that Zofran® readily crosses human placental barriers during pregnancy. GSK has also been aware that the Zofran® animal studies cannot reliably support an assertion that Zofran® can be used safely or effectively in pregnant women.

80. Since 1992, GSK has received hundreds of reports of major birth defects associated with prenatal Zofran® exposure and therefore, GSK has also had actual and/or constructive knowledge that prenatal Zofran® exposure can more than likely double the risk of developing congenital heart defects and/or oral clefts.

81. As alleged below, GSK not only concealed this knowledge from healthcare providers and consumers in the United States, they failed to warn of the risk of birth defects and GSK illegally and fraudulently promoted Zofran® "off-label" to healthcare providers and patients specifically for the treatment of pregnancy related nausea and vomiting.

**GSK's Failure to Warn of the Risk of Birth Defects Associated With Prenatal Exposure to Zofran®**

82. Under federal law regulating GSK's drug labeling for Zofran®, GSK was required to "describe serious adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur." 21 C.F.R. § 201.57(e) (emphasis added).

83. GSK was also required to list adverse reactions and/or adverse events that occurred with other drugs in the same class as Zofran®. *Id.* § 201.57(g).

84. In the context of prescription drug labeling, "an adverse reaction is an undesirable effect, reasonably associated with use of a drug, that may occur as part of the pharmacological action of the drug or may be unpredictable in its occurrence." *Id.*

85. Federal law also required GSK to revise Zofran's® labeling **"to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."** *Id.*, at § 201.57(e) (emphasis added).

86. GSK has received hundreds of reports of birth defects associated with the non-FDA approved use of Zofran® in pregnant women. GSK has failed, however, to disclose these severe adverse events to healthcare providers or expectant mothers, including Karla Rodriguez and her healthcare providers.

87. Under 21 C.F.R. § 314.70(c)(2)(i), pharmaceutical companies were (and are) free to add or strengthen – without prior approval from the FDA – a contraindication, warning, precaution or adverse event.

88. Thus, GSK had the ability and obligation to add warnings, precautions and adverse events to the product labeling for Zofran® without prior approval from the FDA and GSK failed to do so.

89. Under 21 C.F.R. § 201.128, "…if a manufacturer knows, or has knowledge of facts that would give him notice, that a drug introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a drug which accords with such other uses to which the article is to be put."

90. At least as early as 1998, GSK knew from its "off-label" promotion and payments to doctors, its conspicuous increase in revenue from Zofran® and its market analyses of prescription

data that healthcare providers were prescribing Zofran® "off-label" to treat pregnancy related nausea and that such usage was associated with a clinically significant risk or hazard of birth defects.

91. GSK had the ability and obligation to state prominently in the Indications and Usage section of its drug label that there is a lack of evidence that Zofran® is safe for the treatment of pregnancy related nausea. GSK failed to do so despite their knowledge that (a) the safety of Zofran® for use in human pregnancy has not been established; (b) there have been hundreds of reports of birth defects associated with Zofran® use during pregnancy; and (c) epidemiological studies report an increased risk of birth defects in babies exposed to Zofran® during pregnancy.

92. From 1993 to the present, despite mounting evidence of risk of birth defects, GSK's prescribing information has included the same statement concerning use of Zofran® during pregnancy:

> **Pregnancy: Teratogenic Effects**: Pregnancy Category B. Reproduction studies have been formed in pregnant rats and rabbits at I.V. dose up to 4 mg/kg per day and have revealed no evidence of impaired fertility or harm to the fetus due to ondansetron. There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

93. By contrast, the Product Monograph for Zofran® in Canada states "**the safety of ondansetron for use in human pregnancy has not been established,"** and that **"the use of ondansetron in pregnancy is <u>not</u> recommended."**

94. In the United States and in this District specifically, GSK has at all relevant times failed to include any warning disclosing any risks of birth defects arising from Zofran® use during pregnancy in Zofran's® prescribing information or other product labeling.

95. GSK had the ability, and indeed was required, to update Zofran's® label to reflect the reports of positive human fetal risks and injuries.

96. GSK had positive evidence of human fetal risk posed by Zofran® based on more than 200 reports to GSK of birth defects, as well as epidemiological studies and placental-transfer studies reporting on Zofran's® teratogenic risk.

97. The FDA recently promulgated a final rule declaring that as of June 2015 it will require pharmaceutical manufacturers to remove the current A, B, C, D or X pregnancy categorization designation from all drug product labeling and instead summarize the risks of using a drug during pregnancy, discuss the data supporting that summary and describe relevant information to help healthcare providers make prescribing decisions and counsel women about the use of drugs during pregnancy and lactation. 79 Fed. Reg. 72064 (Dec. 4, 2014). In promulgating this rule, the FDA "determined that retaining the pregnancy categories is inconsistent with the need to accurately and consistently communicate differences in degrees of fetal risk."

98. GSK has never updated Zofran's® labeling to disclose that Zofran® can cause fetal harm when administered to a pregnant woman and GSK has failed to warn of the potential hazards to a fetus arising from Zofran® use during pregnancy.

**GSK's Fraudulent, Off-Label Promotion of Zofran® for the Treatment of Pregnancy Related Nausea**

99. At all relevant times, GSK has known that the safety of Zofran® for use in human pregnancy has not been established.

100. With more than six million annual pregnancies in the United States since 1991 and an estimated 70-85% incidence of pregnancy related nausea, there was an extremely lucrative business opportunity for GSK to expand its sales of Zofran® before its patent expiration in 2006. GSK seized that opportunity, but the effect of its conduct was tantamount to experimenting with the lives of unsuspecting pregnant women and their babies throughout the United States and in this District.

101. At least as early as January 1998, despite available evidence showing that Zofran® presented an unreasonable risk of harm to babies exposed to Zofran® prenatally, GSK launched a marketing scheme to promote Zofran® to obstetrics and gynecology (OB/GYN) healthcare providers, including those in this District, as a safe treatment alternative for pregnancy related nausea and vomiting.

102. In support of its off-label marketing efforts, at least as early as January 1998, GSK offered and paid substantial remuneration to healthcare providers and "thought leaders" to induce them to promote and prescribe Zofran® to treat pregnancy related nausea.

103. On March 9, 1999, the FDA's Division of Drug Marketing, Advertising and Communications (DDMAC) notified GSK that the FDA had become aware of GSK's promotional materials for Zofran® that violated the Federal Food, Drug, and Cosmetic Act and its implementing regulations. The FDA reviewed the promotional material and determined that "it promotes Zofran in a manner that is false or misleading because it lacks fair balance." [FDA Letter to Michele Hardy, Director, Advertising and Labeling Policy, GSK, March 9, 1999]

104. GSK's promotional labeling under consideration included promotional statements relating the effectiveness of Zofran®, such as "Zofran Can," "24-hour control" and other promotional messages, but the promotional labeling failed to present any information regarding the risks associated with the use of Zofran® during pregnancy.

105. In its March 9, 1999 letter, the FDA directed GSK to "**immediately cease distribution of this and other similar promotional materials for Zofran that contain the same or similar claims without balancing risk information."** *Id.*

106. GSK disregarded this mandate by the FDA. For example, as early as 2000, GSK's marketing materials in widely circulated obstetric and gynecological trade journals over-emphasized

Zofran's® "Pregnancy Category B" designation as an imprimatur of safeness for use in pregnancy on the very first page of the marketing material and without adequate risk information. This created a false impression to busy healthcare providers that the safety of Zofran® use in pregnancy had been established. GSK's materials failed to disclose any of its internal information concerning the risks of birth defects associated with Zofran® treatment during pregnancy.

107. When the FDA first approved Zofran® to treat cancer patients, GSK's Oncology Division sales force had primary responsibility for marketing and promoting the drug. Beginning in at least January 1998, GSK set out to expand its Zofran® sales to obstetricians and gynecologists by promoting Zofran® as an established safe and effective treatment for pregnancy related nausea. GSK's initial strategy in this regard required its sales force to create new relationships with obstetricians and gynecologists by adding them as "new accounts." While this strategy had some success, it was inefficient compared to a revised promotional strategy that would enable GSK to leverage its other division's already established relationships with obstetricians and gynecologists. Thus, GSK's Oncology Division began partnering with GSK's Consumer Healthcare Division to promote Zofran®.

108. Specifically, in or about 2001, GSK's Oncology Division finalized a co-marketing agreement with GSK's Consumer Healthcare Division under which sales representatives from GSK's Consumer Healthcare Division would market Zofran® to obstetricians and gynecologists. At the time, GSK's Consumer Healthcare Division sales force already had established relationships with, and routinely called on, obstetricians and gynecologists to promote and provide samples of another GSK product, Tums®, specifically for the treatment and prevention of heartburn during pregnancy. GSK's established network for promoting the use of Tums® in pregnancy afforded it an efficient additional conduit for promoting Zofran® for use in pregnancy.

109. GSK's primary purpose in undertaking this co-marketing arrangement was to promote Zofran® to obstetricians and gynecologists during GSK's Consumer Healthcare Division sales force visits to OB/GYN offices. Although some obstetricians and gynecologists performed surgeries and could order Zofran® for post-operative nausea, the central focus of GSK's co-marketing effort was to promote Zofran® for the much more common condition of pregnancy related nausea thereby increasing sales and profits.

110. GSK's Zofran® sales representatives received incentive-based compensation that included an annual salary and a quarterly bonus. The bonus amount was determined by each sales representative's performance in the relevant market and whether he/she attained or exceeded quarterly sales quotas. The more Zofran® sold by a GSK sales representative or prescribed by a provider in that representative's sales territory, the greater the sales representatives compensation and other incentives.

111. As a result of GSK's fraudulent marketing campaign, the precise details of which are uniquely within control of GSK, Zofran® achieved blockbuster status by 2002 and became the number one most prescribed drug for treating pregnancy related nausea in the United States.

112. In 2002, sales of Zofran® in the United States totaled $1.1 billion while global Zofran® sales were approximately $1.4 billion.

113. GSK's promotion of Zofran® for use in pregnancy eventually led to a federal governmental investigation. **On July 2, 2012, the Department of Justice announced that GSK "agreed to plead guilty and pay $3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs" which included Zofran® among numerous others.** [Department of Justice Press Release, *GlaxoSmithKline to Plead Guilty and Pay $3 Billion to Resolve Fraud Allegations and Failure to Report Safety Data* (July 2, 2012)]

114. Part of GSK's civil liability to the government included payments arising from the facts that (a) GSK promoted Zofran® and disseminated false representations about the safety and efficacy of Zofran® concerning pregnancy-related nausea and hyperemesis gravid arum, a severe form of morning sickness and (b) GSK paid and offered to pay illegal remuneration to healthcare professionals to induce them to promote and prescribe Zofran®.

115. GSK's 2012 civil settlement with the United States covered improper promotional conduct that was part of an overarching plan to maximize highly profitable Zofran® sales without due regard to laws designed to protect patient health and safety.

116. In or around 1993, a GSK marketing document sent to all of its sales and marketing personnel nationwide advised that they should emphasize to medical providers not only the benefits of Zofran®, but also the financial benefits to the providers for prescribing Zofran®.

117. Specifically, "[b]y using a 32 mg bag [of Zofran], the physician provides the most effective dose to the patient and increases his or her profit by $___ in reimbursement." GSK's marketing focus on profits to the prescribers misleadingly aimed to shift prescribers' focus from the best interests of the patients to personal profit. In this regard, GSK marketed Zofran® beginning in the 1990s as "convenient" and offering "better reimbursement" to prescribers. GSK detailed this plan in a marketing document for its Zofran® premixed IV bag entitled "Profit Maximization – It's in the Bag." Upon information and belief, GSK's conduct described above continued until the Department of Justice began its investigation.

## FIRST CAUSE OF ACTION
## NEGLIGENCE

118. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

119. Defendant had a duty to exercise reasonable care and comply with existing standards of care in the testing, designing, researching, developing, manufacturing, packaging, promoting, labeling, advertising, marketing, selling and/or distribution of Zofran® into the stream of commerce including a duty to ensure that the product would not cause users to suffer unreasonable and dangerous side effects.

120. Defendant failed to exercise ordinary care and failed to comply with existing standards of care in the testing, designing, researching, developing, manufacturing, packaging, promoting, labeling, advertising, marketing, selling and/or distribution of Zofran® into interstate commerce in that Defendant knew or should have known that using Zofran® created an unreasonable risk of severe birth defects as well as other severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life as well as the need for lifelong medical treatment, monitoring and/or medications.

121. Defendant, its agents, servants and/or employees failed to exercise ordinary care and failed to comply with existing standards of care in the following acts and/or omissions:

a. Failing to conduct adequate testing, including pre-clinical and clinical testing and post-marketing surveillance to determine the safety risks of Zofran® for treating pregnant women while promoting the use of Zofran® and providing kickbacks to healthcare professionals to convince healthcare professionals to prescribe Zofran® for pregnancy related nausea;

b. Marketing Zofran® for the treatment of pregnancy related nausea without testing it to determine whether Zofran® was safe for this use;

c. Designing, manufacturing, producing, promoting, formulating, creating and/or developing Zofran® without adequately and thoroughly testing it;

d. Selling Zofran® without conducting sufficient tests to identify the dangers posed by Zofran® to pregnant women;

e. Failing to adequately and correctly warn Plaintiffs, the public, the healthcare community, including Plaintiff, Karla Rodriguez, and her healthcare providers, as well as the FDA of the dangers of Zofran® in pregnant women;

f. Failing to evaluate available data and safety information concerning Zofran® use in pregnant women;

g. Advertising and recommending the use of Zofran® without sufficient knowledge as to its dangerous propensities to cause birth defects;

h. Representing that Zofran® was safe for treating pregnant women when in fact it was and is unsafe;

i. Representing that Zofran® was safe and efficacious for treating pregnancy related nausea and hyperemesis gravidarum when Defendant was aware that neither the safety nor efficacy for such treatment has been established;

j. Representing that GSK's animal studies in rats and rabbits showed no harm to fetuses when the data revealed impairment of ossification (incomplete bone growth) and other signs of toxicity;

k. Failing to provide adequate warnings regarding birth defects including oral clefts and cardiac malformations;

l. Failing to accompany Zofran® with proper and/or accurate warnings regarding all possible adverse side effects associated with the use of Zofran®;

m. Failing to issue sufficiently strengthened warnings following the existence of reasonable evidence associating Zofran® use with the increased risk of birth defects;

n. Failing to advise Plaintiffs, Plaintiff, Karla Rodriguez's healthcare providers, the FDA and the healthcare community that neither the safety nor the efficacy of Zofran® for treating pregnancy related nausea has been established and that the risks of using the drug for that condition outweigh any putative benefit; and

o. Failing to advise Plaintiffs, Plaintiff, Karla Rodriguez's healthcare providers, the FDA and the healthcare community of clinically significant adverse events (birth defects) associated with Zofran® use during pregnancy.

122. Despite the fact that Defendant knew or should have known that Zofran® significantly increased the risk of birth defects, GSK continued and still continues to negligently market through false and misleading promotion and communication, manufacture, distribute and/or sell Zofran® to consumers including Plaintiff, Karla Rodriguez.

123. Defendant knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of GSK's failure to exercise ordinary care as set forth above.

124. Defendant's negligence was the proximate cause of Plaintiffs' injuries, harm and economic loss which Plaintiffs suffered and/or will continue to suffer.

125. Had Plaintiff, Karla Rodriguez, not taken Zofran®, her baby would not have suffered those injuries and damages as described herein with particularity.

126. As a result of the foregoing acts and omissions, Maia Rodriguez was caused to suffer severe birth defects that are permanent and lasting in nature, physical pain and mental anguish including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medication.

127. Plaintiffs, Karla Rodriguez and Edward Rodriguez, have also sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to their child.

128. As a result of the foregoing acts and omissions, Maia Rodriguez has required and will require future medical care for which she has incurred medical, health, incidental and related expenses. Plaintiffs, Karla Rodriguez and Edward Rodriguez, believe and further allege that their child will in the future be required to obtain further medical and/or hospital care, attention and services.

129. By reason of the foregoing, Plaintiffs have been damaged by Defendant's wrongful conduct. Defendant's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross negligence so as to indicate a complete disregard of the rights and safety of others justifying an award of punitive damages.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such

other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues herein contained be tried by a jury.

**SECOND CAUSE OF ACTION**
**NEGLIGENCE *PER SE***

130. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

131. Defendant had a duty to exercise reasonable care and comply with existing laws in the testing, designing, researching, developing, manufacturing, packaging, promoting, labeling, advertising, marketing, selling and/or distribution of Zofran® into the stream of commerce including a duty to ensure that the product would not cause users to suffer unreasonable and dangerous side effects.

132. Defendant failed to exercise ordinary care and failed to comply with existing laws in the testing, designing, researching, developing, manufacturing, packaging, promoting, labeling, advertising, marketing, selling and/or distribution of Zofran® into interstate commerce in that GSK knew or should have known that using Zofran® created an unreasonable risk of severe birth defects as well as other severe personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life as well as the need for lifelong medical treatment, monitoring and/or medications.

133. Defendant, its agents, servants and/or employees failed to exercise ordinary care and violated 21 U.S.C. § 331m 352l 42 U.S.C. § 1320a-7b; and 21 C.F.R. §§ 201.57, 201.128 in particular.

134. The laws violated by Defendant were designed to protect Plaintiffs and similarly situated persons against the risks and hazards that have occurred in this case. Therefore, Defendant'' conduct constitutes negligence *per se.*

135. Despite the fact that Defendant knew or should have known that Zofran® significantly increased the risk of birth defects, GSK continued and still continues to negligently market through false and misleading promotion and communication, manufacture, distribute and/or sell Zofran® to consumers including Plaintiff, Karla Rodriguez.

136. Defendant knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of Defendant's failure to exercise ordinary care as set forth above.

137. Defendant's negligence was the proximate cause of Plaintiffs' injuries, harm and economic loss which Plaintiffs suffered and/or will continue to suffer.

138. Had Plaintiff, Karla Rodriguez, not taken Zofran®, her baby would not have suffered those injuries and damages as described herein.

139. As a result of the foregoing acts and omissions, Maia Rodriguez was caused to suffer severe birth defects that are permanent and lasting in nature, physical pain and mental anguish including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medication.

140. Plaintiffs, Karla Rodriguez and Edward Rodriguez, have also sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to their child.

141. As a result of the foregoing acts and omissions, Maia Rodriguez has required and will require future medical care for which she has incurred medical, health, incidental and related expenses. Plaintiffs, Karla Rodriguez and Edward Rodriguez, believe and further allege that their

child will in the future be required to obtain further medical and/or hospital care, attention and services.

142. By reason of the foregoing, Plaintiffs have been damaged by Defendant's wrongful conduct. Defendant's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross negligence so as to indicate a complete disregard of the rights and safety of others justifying an award of punitive damages.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues herein contained be tried by a jury.

**THIRD CAUSE OF ACTION**
**STRICT PRODUCTS LIABILITY**
**(Failure to Warn/Design Defect)**

143. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

144. Zofran® was tested, designed, researched, developed, manufactured, packaged, promoted, labeled, advertised, marketed, sold, distributed and/or placed into the stream of commerce by Defendant and was defective at the time it left Defendant's control in that, and not by way of limitation, the drug labeling failed to include adequate warnings, instructions and directions relating to the dangerous risks associated with the use of Zofran® to treat pregnancy related nausea and vomiting. Zofran® was also defective in its design because the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design. Safe and effective products were available for the purpose for which Defendant marketed Zofran®

for use in pregnant women and neither the safety nor the efficacy of Zofran® for that purpose had been established.

145. Defendant failed to provide adequate warnings to healthcare providers and consumers, including Plaintiff, Karla Rodriguez, and her treating healthcare providers of the increased risk of severe birth defects associated with Zofran® and aggressively promoted the product "off-label" to healthcare providers, hospitals and directly to consumers.

146. Prescribing physicians, healthcare providers and pregnant women neither knew nor had reason to know at the time of their use of Zofran® of the existence of the aforementioned severe birth defects. Ordinary consumers would not have recognized the potential risks or side effects for which Defendant failed to include appropriate warnings and which Defendant masked through the unbalanced promotion of Zofran® specifically for treatment in pregnant women.

147. At all times herein mentioned, due to Defendant's "off-label" marketing of Zofran®, the drug was prescribed and used as intended by Plaintiff, Karla Rodriguez, and in a manner reasonably foreseeable to Defendant.

148. GSK is liable to Plaintiffs for the negligent and/or willful failure to provide adequate warnings and other clinically relevant information and data regarding the appropriate use of Zofran® to Plaintiff, Karla Rodriguez, and her healthcare providers.

149. GSK, as a manufacturer of pharmaceutical drugs, is held to the level of knowledge of an expert in the field. Further, GSK knew or should have known that the warnings and other clinically relevant information and data which they distributed regarding the risks of congenital birth defects associated with the use of Zofran® were inadequate.

150. GSK had a continuing duty to provide consumers including Plaintiff, Karla Rodriguez, and her healthcare providers with warnings and other clinically relevant information and data

regarding the risks and dangers associated with Zofran® as it became or could have become available to GSK.

151. Despite the fact that GSK knew or should have known that Zofran® caused unreasonable and severe birth defects, they continued to manufacture, package, promote, label, advertise, distribute and sell Zofran® without stating that there existed safer and more equally effective alternative drug products and/or providing adequate clinically relevant information and data.

152. GSK knew or should have known that consumers and Plaintiffs specifically would foreseeably and needlessly suffer injury as a result of GSK's failures.

153. GSK breached their duty to provide timely and adequate warnings, instructions and information in the following particulars:

a. failing to ensure Zofran® warnings to the healthcare community, physicians, Plaintiff, Karla Rodriguez's healthcare providers and Plaintiffs were accurate and adequate despite having extensive knowledge of the risks associated with Zofran®;

b. failing in their obligation to provide the healthcare community, physicians, Karla Rodriguez's healthcare providers and Plaintiffs with adequate clinically relevant information, data and warnings regarding the adverse health risks associated with exposure to Zofran® and/or that there existed safer and more or equally effective alternative drug products;

c. failing to conduct post-market safety surveillance and report that information to the healthcare community, Karla Rodriguez's healthcare providers and Plaintiffs;

d. failing to include adequate warnings and/or providing adequate and clinically relevant information and data that would alert the healthcare community, Karla Rodriguez's healthcare providers and Plaintiffs to the dangerous risks of Zofran® including among other things the association with congenital birth defects;

e. failing to continually monitor, test and analyze data regarding safety, efficacy and prescribing practices of their marketed drugs including Zofran®;

f. failing to review all adverse drug event information (AER) and to report any information bearing upon the adequacy and/or accuracy of their warnings,

efficacy or safety including the risks and/or prevalence of side effects caused by Zofran® to the healthcare community, Karla Rodriguez's healthcare providers and Plaintiffs;

g. failing to provide adequate post-marketing warnings and instructions after GSK knew or should have known of the significant risks of, among other things, severe congenital birth defects of Zofran®;

h. failing to periodically review all medical literature regarding Zofran® and failing to report data, regardless of the degree of significance, regarding the adequacy and/or accuracy of their warnings, efficacy or safety of Zofran®;

i. failing to disclose the results of the testing and other information in their possession regarding the possibility that Zofran® can interfere with the proper development of an unborn fetus; and

j. failing to warn adequately the healthcare community, the general public and Plaintiffs of the dangers of using Zofran® during pregnancy including the risk of severe congenital birth defects and/or representing that Zofran® was safe for use during pregnancy when in fact GSK knew or should have known that Zofran® was unsafe for this use and that Zofran® was associated with severe congenital birth defects.

154. As a direct and proximate result of the defective nature of Zofran®, Maia Rodriguez was caused to suffer severe birth defects that are permanent and lasting in nature, physical pain and mental anguish including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medication.

155. Plaintiffs, Karla Rodriguez and Edward Rodriguez, have also sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to their child.

156. As a result of the foregoing acts and omissions, Maia Rodriguez has required and will require future medical care for which she has incurred medical, health, incidental and related expenses. Plaintiffs, Karla Rodriguez and Edward Rodriguez, believe and further allege that their child will in the future be required to obtain further medical and/or hospital care, attention and services.

157. By reason of the foregoing, Plaintiffs have been damaged by Defendant's wrongful conduct. Defendant's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross negligence so as to indicate a complete disregard of the rights and safety of others justifying an award of punitive damages.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues herein contained be tried by a jury.

**FOURTH CAUSE OF ACTION**
**FRAUDULENT MISREPRESENTATION**

158. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

159. GSK falsely and fraudulent represented to the expectant mothers and the healthcare community, including Plaintiffs and Plaintiff, Karla Rodriguez's healthcare providers that:

a. Zofran® was safe and effective for treating pregnancy related nausea;
b. Zofran® had been adequately tested and studied in pregnant women;
c. Zofran® use during pregnancy did not increase the risk of bearing children with severe birth defects; and
d. Zofran's® "Pregnancy Category B" designation established the safety and efficacy of Zofran® for treating pregnancy related nausea.

160. These representations made by GSK were material, false and misleading.

161. When GSK made these representations, it knew they were false.

162. GSK made these representations with the intent of defrauding and deceiving the public in general, and the healthcare community in particular, and were made with the intent of inducing the public in general, and the healthcare community in particular, including Plaintiffs and Plaintiff, Karla

Rodriguez's healthcare providers, to recommend, prescribe, dispense and/or purchase Zofran® to treat pregnancy related nausea, all of which evidenced a callous, reckless willful, depraved indifference to the health, safety and welfare of Plaintiffs herein.

163. At the time the aforesaid representations were made by GSK and at the time Plaintiff, Karla Rodriguez, was prescribed and ingested Zofran® during her pregnancy with Maia Rodriguez, she was unaware of the falsity of said representations and reasonably believed them to be true.

164. In reliance upon said representations, Plaintiff, Karla Rodriguez's prescriber was induced to prescribe Zofran® to her and Plaintiff, Karla Rodriguez, was induced to and did use Zofran® to treat pregnancy related nausea.

165. GSK knew that Zofran® had not been sufficiently tested for pregnancy related nausea and that it lacked adequate warnings.

166. GSK knew or should have known that Zofran® increases the risk of severe birth defects.

167. As a result of the foregoing acts and omissions, Maia Rodriguez was caused to suffer severe birth defects that are permanent and lasting in nature, physical pain and mental anguish including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medication.

168. Plaintiffs, Karla Rodriguez and Edward Rodriguez, have also sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to their child.

169. As a result of the foregoing acts and omissions, Maia Rodriguez has required and will require future medical care for which she has incurred medical, health, incidental and related expenses. Plaintiffs, Karla Rodriguez and Edward Rodriguez, believe and further allege that their

child will in the future be required to obtain further medical and/or hospital care, attention and services.

170. By reason of the foregoing, Plaintiffs have been damaged by Defendant's wrongful conduct. Defendant's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross negligence so as to indicate a complete disregard of the rights and safety of others justifying an award of punitive damages.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues herein contained be tried by a jury.

**FIFTH CAUSE OF ACTION**
**FRAUDULENT CONCEALMENT**

171. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

172. In representations to Plaintiff, Karla Rodriguez's healthcare providers, expectant mothers (including Plaintiff, Karla Rodriguez) and the FDA, GSK fraudulently concealed and intentionally omitted the following material facts:

a. GSK was illegally paying and offering to pay doctors remuneration to promote and prescribe Zofran®;

b. Zofran® had not (and has not) been tested or studied in pregnant women at all;

c. *in utero* Zofran® exposure increases the risk of severe birth defects;

d. the risks of severe birth defects associated with the consumption of Zofran® by pregnant women were not adequately tested prior to GSK's marketing of Zofran®;

e. the safety and efficacy of Zofran® for treating pregnancy related nausea has not been established;

f. Zofran® is not safe and effective for treating pregnancy related nausea; and

g. GSK's internal data and information associated Zofran® use during pregnancy with severe birth defects.

173. GSK's concealment and omissions of material facts concerning, among other things, the safety and efficacy of Zofran® for pregnancy related nausea was made purposefully, willfully, wantonly and/or recklessly to mislead physicians, hospital, healthcare providers and expectant mothers including Plaintiff, Karla Rodriguez, into reliance, continued use of Zofran® and to cause them to promote, purchase, prescribe and/or dispense Zofran®.

174. GSK knew that physicians, hospitals, healthcare providers and expectant mothers such as Plaintiff, Karla Rodriguez, had no way to determine the truth behind GSK's concealment and material omissions of facts surrounding Zofran® as set forth herein.

175. Plaintiff, Karla Rodriguez, and her healthcare providers reasonably relied on GSK's promotional statements concerning Zofran's® asserted safety and efficacy in pregnant women from which GSK negligently, fraudulently and/or purposefully omitted material facts.

176. As a result of the foregoing acts and omissions, Maia Rodriguez was caused to suffer severe birth defects that are permanent and lasting in nature, physical pain and mental anguish including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medication.

177. Plaintiffs, Karla Rodriguez and Edward Rodriguez, have also sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to their child.

178. As a result of the foregoing acts and omissions, Maia Rodriguez has required and will require future medical care for which she has incurred medical, health, incidental and related

expenses. Plaintiffs, Karla Rodriguez and Edward Rodriguez, believe and further allege that their child will in the future be required to obtain further medical and/or hospital care, attention and services.

179. By reason of the foregoing, Plaintiffs have been damaged by Defendant's wrongful conduct. Defendant's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross negligence so as to indicate a complete disregard of the rights and safety of others justifying an award of punitive damages.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues herein contained be tried by a jury.

## SIXTH CAUSE OF ACTION
## NEGLIGENT MISREPRESENTATION

180. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

181. GSK falsely and negligently represented to the healthcare community and expectant mothers, including Plaintiff, Karla Rodriguez, and her healthcare providers that:

a. Zofran® was safe and effective for treating pregnancy related nausea;

b. Zofran® had been adequately tested and studied in pregnant women;

c. Zofran® use during pregnancy did not increase the risk of bearing children with birth defects; and

d. Zofran's® "Pregnancy Category B" designation established the safety and efficacy of Zofran® for treating pregnancy related nausea.

182. These representations made by GSK were, in fact, false and misleading.

183. As a result of the foregoing acts and omissions, Maia Rodriguez was caused to suffer severe birth defects that are permanent and lasting in nature, physical pain and mental anguish including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medication.

184. Plaintiffs, Karla Rodriguez and Edward Rodiriguez, have also sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to their child.

185. As a result of the foregoing acts and omissions, Maia Rodriguez has required and will require future medical care for which she has incurred medical, health, incidental and related expenses. Plaintiffs, Karla Rodriguez and Edward Rodriguez, believe and further allege that their child will in the future be required to obtain further medical and/or hospital care, attention and services.

186. By reason of the foregoing, Plaintiffs have been damaged by Defendant's wrongful conduct. Defendant's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross negligence so as to indicate a complete disregard of the rights and safety of others justifying an award of punitive damages.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues herein contained be tried by a jury.

## SEVENTH CAUSE OF ACTION
## BREACH OF EXPRESS WARRANTY

187. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

188. GSK expressly warranted that:

a. Zofran® was safe and effective for treating pregnancy related nausea;

b. Zofran® had been adequately tested and studied in pregnant women;

c. Zofran® use during pregnancy did not increase the risk of bearing children with severe birth defects; and

d. Zofran's® "Pregnancy Category B" designation established the safety and efficacy of Zofran® for treatment of pregnancy related nausea.

189. Zofran® does not conform to these express representations because Zofran® is not safe and presents an unreasonable risk of serious side effects including birth defects and intrauterine death which were not warned about by GSK. As a direct and proximate result of the breach of said express warranties, Plaintiffs suffered and will continue to suffer severe and permanent personal injuries, harm, mental anguish and economic loss.

190. Plaintiff, Karla Rodriguez and her healthcare providers did rely on the express warranties of GSK herein.

191. Members of the healthcare community including physicians and other healthcare professionals relied upon the representations and warranties of GSK for use of Zofran® in recommending, prescribing and/or dispensing Zofran® to treat pregnancy related nausea.

192. GSK knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Zofran® was not safe and fit for the use promoted, expressly warranted and intended by GSK and, in fact, it produced serious injuries to the pregnant women and their babies which injuries were not accurately identified and disclosed by GSK.

193. As a result of the foregoing acts and omissions, Maia Rodriguez was caused to suffer severe birth defects that are permanent and lasting in nature, physical pain and mental anguish

including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medication.

194. Plaintiffs, Karla Rodriguez and Edward Rodriguez, have also sustained severe emotional distress and suffering as a result of GSK's wrongful conduct and the injuries to their child.

195. As a result of the foregoing acts and omissions, Maia Rodriguez has required and will require future medical care for which she has incurred medical, health, incidental and related expenses. Plaintiffs, Karla Rodriguez and Edward Rodriguez, believe and further allege that their child will in the future be required to obtain further medical and/or hospital care, attention and services.

196. By reason of the foregoing, Plaintiffs have been damaged by Defendant's wrongful conduct. Defendant's conduct was willful, wanton, reckless and, at the very least, arose to the level of gross negligence so as to indicate a complete disregard of the rights and safety of others justifying an award of punitive damages.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues herein contained be tried by a jury.

## EIGHTH CAUSE OF ACTION
## BREACH OF IMPLIED WARRANT OF MERCHANTABILITY AND FITNESS FOR PARTICULAR USE

197. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

198. Defendant is a merchant with respect to goods of the kind Plaintiff, Karla Rodriguez, received. Defendant impliedly warranted that its product was merchantable. Defendant impliedly warranted that its product was fit for the particular purpose of being used safely in the treatment of pregnancy related nausea. Plaintiff, Karla Rodriguez, and her healthcare providers relied on Defendant's skill and judgment when deciding to use Defendant's product.

199. Defendant's product, Zofran®, was not fit for the ordinary purpose for which such goods were used. It was defective in design and its failure to provide adequate warnings and instructions and was unreasonably dangerous. Defendant's product was dangerous to an extent beyond the expectations or ordinary consumers with common knowledge of the product's characteristics including Plaintiff, Karla Rodriguez, and her healthcare providers.

200. Defendant breached its implied warranties because the product was not safe, not adequately packaged and labeled, did not conform to representations Defendant made and was not properly usable in its current form according to the labeling and instructions provided.

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor for compensatory and punitive damages together with interest, costs herein, attorneys' fees and all such other and further relief as this Court deems just and proper. Plaintiffs also demand that the issues herein contained be tried by a jury.

**DEMAND FOR JURY TRIAL**

Plaintiffs demand trial by jury pursuant to Rule 38 of the Federal Rules of Civil Procedure and the Seventh Amendment of the United States Constitution.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs demand judgment against Defendant on each of the above-referenced claims and causes of action and as follows:

a. For general damages in a sum in excess of the jurisdictional minimum of this Court;

b. For medical, incidental and hospital expenses according to proof;

c. For pre-judgment and post-judgment interest as provided by law;

d. For full refund of all purchase costs of Zofran®;

e. For consequential damages in excess of the jurisdictional minimum of this Court;

f. For compensatory damages in excess of the jurisdictional minimum of this Court;

g. For punitive damages in an amount in excess of any jurisdictional minimum of this Court in an amount sufficient to deter similar conduct in the future and punish the Defendant for the conduct described herein;

h. For attorneys' fees and costs of this action; and

i. For equitable relief and such other and further relief as this Court deems necessary, just and proper.

/s/ Kimberly D. Barone Baden
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Attorneys for Plaintiffs

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